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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/167,516	10/06/98	CHEEVER	M 920010.44808

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SEED INTELLECTUAL PROPERTY LAW GROUP PLL  
701 FIFTH AVE  
SUITE 6300  
SEATTLE WA 98104-7092

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

13

DATE MAILED:

11/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/167,516

Applicant(s)  
Cheever et al

Examiner  
Karen Canella

Group Art Unit  
1642



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 7-12 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 7-12 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### DETAILED ACTION

- ~~1. Applicant's election of Group IV in Paper No. 11 is acknowledged. Because applicant did~~  
not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-6 have been canceled. Claim 7 has been amended. Claims 10-12 have been added. Claims 7-12 are pending and examined on the merits.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for eliciting or enhancing an immune response to Her-2/neu protein comprising administering to a warm-blooded animal a Her-2/neu polypeptide, does not reasonably provide enablement for a method for eliciting or enhancing an immune response to Her-2/neu protein comprising administering to a warm-blooded animal a Her-2/neu polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.  
(A) As drawn to polynucleotides consisting of nucleotides 2026 through 3765 of SEQ ID NO:1  
Claim 7 is drawn to a method for eliciting or enhancing an immune response to Her-2/neu

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protein comprising administering to a warm-blooded animal in an amount effective to elicit or enhance said response a nucleic acid molecule or the viral vector that directs the expression of a polypeptide encoded by a DNA sequence selected from nucleotides 2026-3765 of SEQ ID NO:1, the region of the cDNA sequence of the Her-2 gene represents the non-extracellular portion of the Her-2 protein. a method for eliciting or enhancing an immune response to Her-2/neu protein comprising administering to a warm-blooded animal a Her-2/neu polynucleotide. The specification teaches that the protein expressed from nucleotides 2026-3765 of SEQ ID NO:1 is effective in priming dendritic cells which can induce the proliferation of autologous Cd+4 T cells in vitro. The specification teaches that rats immunized with Her-2/neu polypeptide develop neu specific antibodies. The specification does not teach the administration of nucleotides 2026-3765 of SEQ ID NO:1 to elicit or enhance an immune response to Her-2/neu. One cannot extrapolate the teaching of the specification to the claims because it is well known that the administration of nucleic acids into a host is highly unpredictable. Injection of naked DNA is limited to striated muscle which is found to take up and express genes that are transferred in the form of plasmid DNA, but that fibers damaged by the injection procedure do not take up and express plasmid DNA (Davis et al, Human Gene Therapy, 1993, vol. 4, pp. 151-159). In addition, use of intramuscular injections, when successful, can produce high levels of protein expression which can result in toxicity in the host cell. Further, use of a viral vector or host cell transfected ex vivo to deliver the desired polynucleotides can present potential health risks associated with damage to the genetic material in the host cell. The specification discusses only a method for eliciting or enhancing an immune response to Her-2/neu protein comprising administering to a warm-blooded animal a Her-2/neu polypeptide and does not provide any instruction for the administration of a polynucleotide to elicit or enhance the immune response to the Her-2/neu protein. The specification provides no direction as to tissue specific targeting or tumor specific targeting (Wickham, T.J., Gene Therapy, 2000, vol. 7, pp. 110-114) that would protect normal cells from being destroyed by the immune system after expression of the Her-2/neu polypeptide. The

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specification provides no guidance on the deleterious or non-deleterious effect of over-expressing in normal tissue the Her-2/neu polypeptide, which has been characterized as having an intracellular tyrosine kinase domain that is necessary for transformation. The specification provides no direction as to the replication competence of the viral vector for the delivery of the polynucleotide and the persistence time of the virus in humans necessary for the claimed efficacious immune response (Crystal, R.G., Cancer Chemotherapeutics and Pharmacology, 1999, Vol. 43 Suppl., pp. S90-S99). It is the Examiner's position that due to the reasons set forth above regarding the unpredictability of the art, and the lack of guidance presented in the specification, one of ordinary skill in the art is unable to practice the invention to the full scope of the claims.

(B) As drawn to DNA sequences that hybridize to a polynucleotide sequence complementary to nucleotides 2026 through 3765 of SEQ ID NO:1

Claim 7 is drawn to a method for eliciting or enhancing an immune response to Her-2/neu protein comprising administering to a warm-blooded animal polynucleotides which hybridize under moderately stringent conditions to nucleotides 2026-3765 of SEQ ID NO:1, wherein the polynucleotides encode a polypeptide that produces an immune response to Her-2/neu protein. Given the broadest reasonable interpretation, the claim is drawn to non-disclosed polynucleotides in addition to polynucleotides that encompass degenerate codon sequences of nucleotides 2026-3765 of SEQ ID NO:1 that encode polypeptides which produce an immune response to Her-2/neu protein. The specification discusses only the polypeptide encoded by nucleotides 2026-3765 of SEQ ID NO:1. The specification does not teach smaller fragments of the polypeptide encoded by nucleotides 2026-3765 of SEQ ID NO:1, nor does the specification teach polypeptide variants of the polypeptide encoded by nucleotides 2026-3765 of SEQ ID NO:1 that would be encoded from variant polynucleotide sequences which would hybridize to nucleotides 2026-3765 of SEQ ID NO:1 under moderately stringent conditions. The specification has not identified what is structurally necessary in the polypeptide encoded by nucleotides 2026-3765 of SEQ ID NO:1 to evoke the desired immune response to Her-2/neu protein, therefore, one of skill in the art would

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not be able to anticipate which polynucleotide sequences, if any, that hybridize to nucleotides 2026-3765 of SEQ ID NO:1 would encode the claimed polypeptides without undue experimentation.

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*Conclusion*

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

October 22, 2000



**GEETHA P. BANSAL  
PRIMARY EXAMINER**